REMARKS

I. Claim Status

Claims 31-32 were previously cancelled. Claims 36-39 and 41 were withdrawn from consideration by the Office. Claims 43-51 are new. With the entry of this Amendment, claims 24-30, 33-35, 40, and 42-51 are currently under consideration. Applicant addresses the objections and rejections below.

II. Amendments to the Claims

Claims 24, 25, 27, 28, and 30 were amended to claim more clearly the isolated or purified oligopeptide or polypeptide of the invention, as disclosed in the specification. The amended claims find support in the specification, for example, on pages 1, 11-13, 45, and Figure 5.

Claims 33, 34, 40, and 42 were amended to remove their dependency from claim 31. None of the amendments introduced new subject matter.

Claims 43-51 derive from the specification as filed (and amended in the reply dated August 11, 2008) at, for example, pages 16-17, and page 35. Thus, none of the new claims adds new matter.

III. Claim Objections

The Office objected to claim 28 because of the alleged following informality that "'at least one of the amino acid found at positions. . . .,' should read -- at least one of the amino acids found at positions . . . .--." Office Action, page 2. Applicant has amended the claim to such that this rejection is now moot. Applicant respectfully requests that the objection is withdrawn.

IV. Rejections Under 35 U.S.C. § 101: Non-Statutory Subject Matter

Applicant thanks the Examiner for withdrawing the previously asserted rejection of claims 24-33, and 40 under 35 U.S.C. § 101 as being allegedly directed to non-statutory subject matter. See Office Action, page 2.

V. Rejections Under 35 U.S.C. § 112 ¶ 2: Indefiniteness

The Office maintained the previous rejection of claims 28, 30-35, 40, and 42 under 35 U.S.C. § 112 ¶ 2 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Office Action, page 3-4.

The Office treated claim 28 as representative. According to the Office, claim 28 reads on a peptide comprising "at least 5 consecutive amino acids from SEQ ID NO:12, and comprising 'at least one of the amino acids found at' the indicated amino acid positions of that sequence." Office Action, page 3. The Office re-asserts that it was not clear before—and Applicant's amendment was not found sufficient to clarify—if the claim is requiring that the consecutive amino acid sequence from SEQ ID NO:12 includes the indicated amino acid position, or if the claim is requiring a consecutive sequence from SEQ ID NO:12, and an amino acid position corresponding to that identified amino acid positions. The Office further asserted that it was not clear what is meant by the language requiring that the polypeptide comprises one of the indicated amino acid positions. As an example, the Office alleged that it is not clear if the claim is requiring that the polypeptide includes a position 73, includes a position 73 having the same amino acid that is found in position 73 of SEQ ID NO:12, or if the polypeptide need only include the amino acid found in the position 73 of SEQ ID NO:12. Office

Action, page 3. The Office requests clarification of the scope of the claims. Office Action, page 4.

Applicant respectfully traverses this rejection, for the reasons already of record. Furthermore, as explained in the specification (see, for example, pages 12 and 13), the oligopeptide or polypeptide of the invention of claim 28 (as amended herein), comprises a constituent sequence, or a "fragment of SEQ ID NO:12," which is one of the recited "sequences of at least 6 consecutive amino acids." That fragment/constituent sequence that is a portion of SEQ ID NO:12 also includes at least one of the positions 73, 78, 112, 122, and 139 of SEQ ID NO: 12. One of skill in the art would understand that, as is implicit from the claims, if the fragment with a sequence at least 6 consecutive amino acids from SEQ ID NO:12 includes position 78 of SEQ ID NO:12, then it must be a fragment of the constituent sequence that consecutively expands from position 78. It can do so to the left of that position 78 towards position 73 (i.e. 78-5=73) of SEQ ID NO: 12; to the right of position 78 towards position 83 (i.e. 78+5=83) of SEQ ID NO: 12; or to both sides (such as a sequence that would span 75-80). Similar simple math applies to the other positions. Thus, in contrast to the Office's contention that the claims are indefinite, the oligopeptide or polypeptide claimed is definite. Solely to expedite prosecution, however, and without acquiescing to the rejection, Applicant amends independent claim 28, and further clarifies the scope of the claims by explicitly reciting this information. Support for the amended claim can be found throughout the specification, for example, on page 12-13 of the specification as filed. Applicant submits that the amended claim complies with

the statutory subject matter requirements. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. § 112 ¶ 2.

The Office also rejected claims 33-35, 40, and 42, on the grounds that these claims improperly depend on a cancelled claim. Applicant thanks the Examiner for pointing out this typographical error, and has amended these claims accordingly to remove their dependency from claim 31. Applicant submits that the amended claims comply with the statutory subject matter requirements. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. § 112 ¶ 2.

VI. Rejections Under 35 U.S.C. § 112 ¶ 1: Written Description

The Office maintained the rejection of claims 25, 40, and 42 under 35 U.S.C. § 112 ¶ 1, and further extends it to claim 27 "for the same reasons as indicated with respect to claims 25, 40, and 42 in the prior action," as allegedly failing to comply with the written description requirement. Office Action, pages 4-5.

According to the Office, claim 25 is drawn to a genus of polypeptides comprising any polypeptide that is at least 94% identical to SEQ ID NO:13 (a fragment of the Hepatitis B surface antigen-HBsAg from HBV variant HDB 05), and that retains the ability to bind to sera from an individual infected with HBV variant HDB 05. Office Action of October 8, 2008, pages 5-6. Claims 40 and 42 read on kits or methods for the use of polypeptides that are at least 94% identical to SEQ ID NO:13 for the purpose of detecting antibodies against HBV. Office Action of October 8, 2008, pages 5-6. The Office took the position that these claims therefore implicitly require that the polypeptides are capable of binding sera from HBV infected patients (or at least

antibodies that bind to HBV) and are drawn to a genus of polypeptides having a sequence of at least 94% identity to SEQ ID NO:13, wherein the polypeptides react with either HBV or HBV variant HDB 05 reactive sera. Office Action of October 8, 2008, page 6. The Office also previously asserted that the application indicates that SEQ ID NO:13 itself does not react to anti-HBV antibodies generally and fails to identify any variants of SEQ ID NO:13 that bind to either anti-HBV or anti-HBV HDB 05 antibodies. Finally, the Office also previously asserted that there is significant uncertainty as to the ability of mutants of SEQ ID NO:13 to react with antibodies directed to either HBsAg proteins comprising SEQ ID NO:13 or to HBsAg proteins from other HBV variants. Office Action of October 8, 2008, page 8.

In this Office Action, the Office asserted that the arguments raised by Applicants in response to the previous rejection were not found persuasive. The Office therefore maintained its rejection of the claims as lacking adequate descriptive support for the claimed genus of polypeptide comprising mutants of SEQ ID NO:13, and further extended it to claim 27, "for the same reasons as indicated with respect to claims 25, 40, and 42 in the prior action." Office Action, page 5. In addition, the Office asserted that there is significant uncertainty in the identity of what peptides sharing at least 94% identity to SEQ ID NO:13 would retain that ability to react with sera from the indicated population of donors and that the Applicant "makes no argument and presents no evidence in traversal of these concerns." Office Action, page 5.

Applicant respectfully traverses this rejection for the reasons set forth in the Amendment and Response filed on April 8, 2008, and for those additionally set forth below. In making the written description rejection, the Office has overlooked that written

description support does not require absolute, word-for-word support in a patent application text. In fact, literal support is not even the standard, as claims may also be supported implicitly or impliedly from the application as a whole. "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." M.P.E.P. § 2163. Possession can be demonstrated by "describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." *Id.* (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)).

As amended, claim 25 is directed to an isolated or purified oligopeptide or polypeptide comprising an amino acid sequence with at least 94% identity to SEQ ID NO:13, wherein the oligopeptide or polypeptide binds immunologically to sera from individuals who are infected with the hepatitis B variant HDB 05. Because claim 25 depends from claim 24, the isolated or purified oligopeptide or polypeptide also must meet the following limitations:

> (i) from 0 to 4 amino acids are substituted, deleted, or inserted as compared with SEQ ID NO:13, and
>
> (ii) at least one of the five amino acid substitutions in the S antigen of the hepatitis B variant HDB 05 as compared to the HBV adw wild type is preserved, wherein said substitutions are chosen from T 115 (R), P 120 (Q), S 154 (L), E 164 (V), and Q 181 (R).

The claim satisfies the written description requirement because a skilled artisan could identify all of the polypeptides sharing at least 94% sequence identity with SEQ ID

NO:13 that meet this additional limitation. These sequences were contemplated by the inventors as within the scope of their invention, and the specification teaches the relationship between the structure of these sequences and their function.

For example, the specification describes the claimed invention as a novel sequence having 5 amino acid substitutions in the in the S antigen of the hepatitis B variant HDB 05, as compared to the HBV adw wild type, said substitutions identified as T 115 (R), P 120 (Q), S 154 (L), E 164 (V), and Q 181 (R) with 4 substitutions being located in the region of the "*a determinant*" (aa 101 to aa 180) and 1 substitution in the direct vicinity thereof (aa 181). (See specification, page 1 and Example 4 on page 45, as well as Figure 5.) The amino acid sequence shown in SEQ ID NO:13 corresponds to amino acid positions 111 to 185 of HBsAg. (See specification, page 10; and amendment to page 12 of the specification dated August 11, 2008). SEQ ID NO:13 comprises the "*a determinant*" which acts as the binding sites for antibodies. Also, SEQ ID NO:13 (which is 75 amino-acids-long) having from 0 to 4 substitutions in the "*a determinant*" would result in a mutant of SEQ ID NO:13 being at least 94% identical to SEQ ID NO:13. Moreover, the claim requires that, even if the maximum number of 4 substitutions, deletions, or insertions, are made to SEQ ID NO:13, at least one of the mutations that Applicant identified in the region corresponding to the "*a determinant*" of HBsAg in the HDB 05 variant must still be preserved in the remaining isolated or purified oligopeptide or polypeptide of claim 25 (and dependent claims 40 and 42). Again, these are corresponding substitutions T 115 (R), P 120 (Q), S 154 (L), E 164 (V), and Q 181 (R), respectively represented in SEQ ID NO:13 positions 73, 78, 112, 122, and 139 (*See, e.g.*, specification at page 12, and amendment dated August 11, 2008).

Finally, the specification provides that the "invention also related to antibodies which react with the a determinant described in SEQ ID NO: 11 to 22, with the binding preferably taking place in the amino acid region aa 115 to 120, aa 154 to 164 or aa 154 to 185." (Specification, page 35). Accordingly, Applicant also provides new claims 42-51, which are directed to narrower embodiments of claims 24 and 25 also contemplated by the Applicant. In these narrower embodiments, Applicant further specifies structural limitations that are linked to the immunogenic properties of the claimed polypeptides, and/or further defines the functional properties of the claimed polypeptides.

With that guidance as background, and for at least the reasons that follow, one of skill in the art reading the specification and the claims as a whole, would understand that the Applicant was in possession of the invention just described.

First, the specification also provides that, "after an infection with HBV, the immune response is principally directed against what is termed the *'a determinant,'* as a region of the S protein . . . the most heterogeneous part of the B cell epitopes of the S gene" and that the "*a determinant*" corresponds to positions 101-180 of the S protein. *See, e.g.*, Specification at page 4 line 35-page 5, line 5 (emphasis added). Moreover, the specification also provides that "99% of so-called 'protective antibodies,' which circulate in serum after a natural infection with HBV, are directed against the very immunogenic a determinant of the HBV." Specification, page 5. Four of the 5 amino acid positions that Applicant's newly identified in HDB 05 are in its "*a determinant*" region, and at least one of them must be retained in the in the oligopeptides or polypeptides of claim 25 (an "*a determinant*" sequence). Specification at Figure 5.

Second, the oligopeptides or polypeptides of claim 25, being related to SEQ ID NO:13 (positions 111 to 185) come from this "*a determinant*" region, a region whose structure is well known to be linked to immunogenicity. Therefore, one of skill in the art would expect them to produce an immune response. In fact, that is how Applicants discovered the HDB 05 variant. As the specification provides, sera from patients infected with the HDB 05 variant contained antibodies that "indicated an acute HBV infection" and yet the sera did not react with a kit for detection of previously known S antigen. Specification, pages 9-10. Accordingly, the specification provides that Applicants discovered that the HDB 05 variant differed from previously known S antigens in 5 residues, 4 of which are located in the "*a determinant*" and one immediately next to it. *See, e.g.*, Specification, page 12. Moreover, even with respect to the substitution outside the "*a determinant*," the Q 181 (R) substitution, corresponding to SEQ ID NO:13 position 139, the specification explicitly provides that "[s]ince it is known that epitopes on the a determinant are occasioned structurally, that is can be present as what are known as conformational epitopes, it seems likely that the immunogenicity, and also the ability of antibodies to bind to the a determinant, can be influenced by the amino acid substitution in position 181." Specification, page 10.

Lastly, the oligopeptides or polypeptides of claim 25 must (i) possess the specified activity of "reacting with sera from individuals who are infected with the . . . variant HDB05" and (ii) must have at least 94% identity to the reference sequence, SEQ ID NO:13 and (iii) preserve at least one of the five amino acid positions of SEQ ID NO:13 that correspond to the five amino acid substitutions in the S antigen of the hepatitis B variant HDB 05 as compared to the HBV adw wild type, said substitutions

identified as T 115 (R), P 120 (Q), S 154 (L), E 164 (V), and Q 181 (R). Consequently, the genus of oligopeptides or polypeptides of claim 25 must meet both one functional and two structural requirements. Consequently, the genus does not have substantial variation. Applicants provide an assay for identifying all of the at least 94% identical variants of SEQ ID NO:3 that preserve at least one of the five amino acid positions of SEQ ID NO:13 that correspond to the five amino acid substitutions in the S antigen of the hepatitis B variant HDB 05 as compared to the HBV adw wild type, said substitutions identified as T 115 (R), P 120 (Q), S 154 (L), E 164 (V), and Q 181 (R)(structural requirement) and an assay for identifying those that are capable of the specified activity of "reacting with sera from individuals who are infected with the . . . variant HDB05" (functional requirement). One of skill in the art would conclude that Applicants were in possession of the necessary common attributes possessed by the members of the genus.

Accordingly, the specification adequately describes the recited genus and a person skilled in the art can "visualize or recognize the identity of the members of the genus" under the standard of *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997). Thus, in contrast to the Office's contention that the claims fail to comply with the written description requirement, the claims are fully supported by the application. Support for the claims can be found throughout the specification. Applicant submits that the amended claims comply with the written description requirements. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. § 112 ¶ 1.

VII. Rejections Under 35 U.S.C. § 112 ¶ 1: Enablement

The Office maintained its rejection of claims 24, 26, 33-35, 40, and 42 under 35 U.S.C. § 112 ¶ 1 as allegedly lacking enablement for the use of any polypeptide comprising an amino acid sequence of at least 94% identity to SEQ ID NO:13. Applicant respectfully traverses this rejection for the reasons set forth in the Amendment and Response filed on April 8, 2008, and for those additionally set forth below.

Previously, the Office asserted that "the specification, while being enabling for polypeptides comprising SEQ ID NO:13, does not reasonably provide enablement for the use of any polypeptide comprising an amino acid sequence of at least 94% identity to that sequence. The specification does not enable any person skilled in the art . . . to use the invention commensurate in scope with these claims." Office Action of October 8, 2008, page 8. After setting forth an analysis based on *In Re Wands'* eight factors, the Office concluded that "[i]n view of the breadth of the claims, the limited provision of working examples and the limited disclosure regarding the structure and functional and antigenic properties of the HBsAg comprising SEQ ID NO:13, and the uncertainty and unpredictability in the art, **the indicated claims are rejected because there is insufficient information provided to enable those in the art to use the claimed peptides without undue experimentation**. Office Action of October 8, 2008, page 10 (emphasis added).

In the Reply dated April 8, 2009, Applicant noted that in making the enablement rejection, the Office improperly used "working example" to limit scope of claim. Moreover, the specification is enabling where it teaches "those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation."

Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365, 42 U.S.P.Q.2d 1001, 1004 (Fed. Cir. 1997). However, "[e]nablement is not precluded by the necessity for some experimentation such as routine screening." *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Applicant set forth separate portions of the specification that, when combined with the knowledge in the art, would show that Applicant provided guidance to enable the skilled artisan to make and use the claimed proteins.

Yet, the Office alleges that Applicant's arguments were not found persuasive. The Office alleges that "Applicant traverses the rejection on the basis that those in the art would be able to determine what variants retain the activity of SEQ ID NO:13; because, while biotechnology may be an unpredictable art, such does not preclude a finding of enablement; and because those in the art would be able to identify all of the nucleic acids encoding a polypeptide sharing at least 94% sequence identity with SEQ ID NO:13 and screen them for the sharing activity with SEQ ID NO: 13."

Furthermore, according to the Office, "Applicant's arguments may be found persuasive if the rejection was based on a finding of lack of enablement based on a consideration of only one or two of the factors identified in the prior action." Office Action, page 9. However, the Office alleges, "in the present case, the claims are broadly drawn to cover a large number of mutant sequences, the structures and functions of which are not known, and cannot easily be predicted, and where the application itself provides little information with respect to the functions or structure of the protein of SEQ ID NO:13, and no identification or characterization of mutants thereof." Office action, page 6. The Office concludes asserting that "while those in the

art may be capable of performing screening assays, and as certain forms of screening may be routine, the teachings in the application nonetheless fail to provide enabling support for the full scope of the invention. The rejection is therefore maintained." Office Action, page 6. For at least the reasons already set forth in the Reply of April 8, 2008, Applicant respectfully disagrees. This rejection is now moot due to the amendments to claims 24 and 26. Solely to expedite prosecution, however, and without acquiescing to the rejection, Applicant amends independent claims 24 and 26.

As amended herein, independent claim 24 and 26 encompass a smaller number of sequences than the previously presented claims, at least because they recite the following additional limitation (claim 26 recited "at least two," instead of "at least one"):

> ***at least one*** of the five amino acid substitutions in the S antigen of the hepatitis B variant HDB 05 as compared to the HBV adw wild type is preserved, wherein said substitutions are chosen from T 115 (R), P 120 (Q), S 154 (L), E 164 (V), and Q 181 (R).

Having at least one of these substitutions in common with SEQ ID NO:13 is believed to preserve an activity of that sequence (i.e., reactivity with sera from individuals infected with the hepatitis B variant HDB 05). *See, e.g.*, original claim 2 together with the recitation in item (d) of original claim 1. By this amendment, less experimentation, and certainly not undue experimentation, is required of the skilled artisan to make and use invention as claimed in amended claims 24 and 26. First, the "breadth of the claims" (the last of the eight Wands' factors) is narrower and consequently a lesser "quantity of experimentation" (the first Wands' factor) is required from one of skill in the art. Moreover, the claims themselves offer more guidance as to the number and the identity of the amino acids that can and cannot be substituted,

deleted, or inserted relative to SEQ ID NO:13, to enable their use. Applicant also added a set of new claims 43-51, further breaking down the scope of the various embodiments whose use was envisioned by the Applicant and disclosed in the specification.

The skilled artisan could use the proteins of claim 24 and 26 as part of an S protein and/of an *"a determinant"*. Indeed, the specification sets forth that SEQ ID NO:13 is an isolated fragment encompassing the "*a determinant"* of the larger S protein from an hepatitis B virus that was capable of infecting a patient such that the patient "had contracted inflammation of the liver" with "liver values which were typical for such an infection." *See, e.g.*, Specification, page 9. Consequently, the S protein from which SEQ ID NO:13 was isolated has at least one function (to act as S protein) and the *a antigen* does appear to have acted as an *a antigen* because there was an immune response in the patient and, as stated above, the specification notes that "99% of so-called 'protective antibodies', which circulate in serum after a natural infection with HBV, are directed against the very immunogenic a determinant of the HBV." Specification, page 5. In fact, the specification notes that "HDB 05 is a replication-capable and infectious mutant or variant of HBV . . . ." Specification, page 10. Thus, with this information, one of skill in the art would be able to use the protein of SEQ ID NO:13 for various purposes, including at least as a part of an S protein and/of an *a antigen*.

The specification also provides that "it is possible to use the *a determinant of the HDB 05 variant* according to the invention, *in the form of the entire polypeptide sequence or parts thereof*, for determining antibodies which are directed against the HBV variant: anti-HBs antibodies." Specification, page 30 (emphasis added). Moreover, it provides that "[t]he skilled person is familiar with a large number of

determination methods in which immune complexes are formed, or their formation is inhibited, *using polypeptides from the a determinant of the HBV variant* and antibodies of animal or human origin." Specification, page 22 (emphasis added). Thus, the specification provides at least two additional functions for the oligopeptide or polypeptide of SEQ ID NO:13.

When combined with the knowledge in the art, the specification provides substantial guidance to enable the skilled artisan to make and use the claimed proteins. A skilled artisan could apply the teachings of the specification to additional species and practice the claimed kit by following the direction provided by the specification without undue experimentation. Thus, in contrast to the Office's contention that the claims fail to comply with the enablement requirement, the claims are fully supported by the application. Support for the claims can be found throughout the specification. Applicant submits that the amended claims comply with the enablement requirement. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. § 112 ¶ 1.

VIII. Rejections Under 35 U.S.C. § 102(b)

A. Anticipation over Quinnan *et al.* (WO 00/07631)

Applicant thanks the Examiner for withdrawing the previously asserted rejection of claims 28 and 31 under 35 U.S.C. § 102(b) as allegedly being anticipated by Quinnan *et al.* (WO 00/07631). See Office Action, page 7.

B. Anticipation over Langley *et al.* (EP 0533492)

The Office maintained its previous rejection of claims 28, 33-35, and 40 under 35 U.S.C. § 102(b) as allegedly being anticipated by Langley *et al.* (EP 0533492). The

Office also was not "persuaded by Applicant's arguments regarding the clarity of the claims." Office Action, page 7. The Office asserted the position that the broadest reasonable interpretation of the claims appears to read on any polypeptide containing at least 6 consecutive amino acids of SEQ ID NO:12, wherein the amino acids comprise one of the amino acids Ser, Gln, Leu, Val, or Arg. Office Action, page 7.

The Office newly asserted that Langley anticipates the indicated claims because it teaches a polypeptide containing at least 6 consecutive amino acids of SEQ ID NO:12, wherein the amino acids comprise one of the amino acids Ser, Gln, Leu, Val, or Arg. The Office also more specifically alleged that Langley teaches a polypeptide comprising a sequence of at least six consecutive amino acids of SEQ ID NO:12, wherein the sequence comprises the amino acid found at position 73 of SEQ ID NO:12 (i.e. an Arginine), and also which sequence is found in amino acids 29-34 of SEQ ID NO:12. Langley, Figure 1 (sequence of the sixth line of amino acids beginning Gly Tyr Arg Trp Met Cys). The Office also previously asserted that Langley anticipates the indicated claims because it teaches the recombinant production and purification of the protein. (Langley, pages 6-7.)

Applicant respectfully traverses this rejection. This rejection is now moot due to the amendments to claim 28. As amended, claims 28 now recites, in relevant part (emphasis added):

> An isolated or purified oligopeptide or polypeptide comprising a fragment of SEQ ID NO:12, wherein the ***fragment of SEQ ID NO:12*** comprises at least one of the following sequences:

> (i) a sequence of at least 8 consecutive amino acids that includes amino acid position 73 of SEQ ID NO:12 and ***is found within positions 66-80 of SEQ ID NO:12***; . . .

As the Office pointed out, Langley's sequence is found in amino acids 29-34 of SEQ ID NO:12. However, it is not found within positions 66-80 of SEQ ID NO:12, as amended claim 28 recites. The following table emphasizes this difference; only amino acid position 73, the Arg, is in common.

Pos. No.	66	67	68	69	70	71	72	**73**	74	75	76	77	78	79	80
SEQ ID NO:12	P	L	I	P	G	S	T	**R**	T	S	T	G	Q	C	K
Langley's Sequence						G	Y	**R**	W	M	C	T			

Any fragment of SEQ ID NO:12 consisting of a sequence of at least 8 consecutive amino acids from SEQ ID NO:12 that includes the R at amino acid position 73 must include consecutive with the R at least one of positions 74 or 72 as well. In other words, it must either include a TR or a RT sequence. Langley's GYRWMCT fragment does not include either sequence. Therefore, Langley does not anticipate any of claims 28, 33-35, and 40. Applicant submits that the amended claims are sufficiently clear and overcome the anticipation rejection. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b).

Applicant submits that the amended claims overcome the anticipation rejection. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b).

C. Anticipation over GenPept BAC17521

The Office newly rejected claim 28 as allegedly anticipated GenPept BAC17521, residues 562-568. See Office Action, page 8.

Applicant respectfully traverses this rejection. This rejection is now moot due to the amendments to claims 28. As amended, claims 28 now recites, in relevant part (emphasis added):

> An isolated or purified oligopeptide or polypeptide comprising a fragment of SEQ ID NO:12, wherein the ***fragment of SEQ ID NO:12*** comprises at least one of the following sequences:
>
> (i) ***a sequence of at least 8 consecutive amino acids*** that includes amino acid position 73 of SEQ ID NO:12 and ***is found within positions 66-80 of SEQ ID NO:12***; . . .

As the Office pointed out, GenPept BAC17521's relevant sequence is found in amino acids 71-77 of SEQ ID NO: 12. However, it is **not a sequence of at least 8 consecutive amino acids, said sequence found within positions 66-80 of SEQ ID NO:12**, as amended claim 28 recites. The following table emphasizes this shortcoming of GenPept BAC17521; the common sequence is only 7 amino acids long, not 8 as the claim recites.

Pos. No.	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80
SEQ ID NO:12	P	L	I	P	**G**	S	T	R	T	S	T	G	**Q**	C	K
GenPept BAC17521 Sequence					T	S	T	R	T	S	T	G	**T**		

Any fragment of SEQ ID NO:12 consisting of a sequence of at least 8 consecutive amino acids from SEQ ID NO:12 that includes the R at amino acid position 73 must include more than the seven consecutive STRTSTG of GenPept BAC17521; it

must include the additional consecutive **G** (i.e., be **G**STRTSTG) or the additional consecutive **Q** (i.e., be STRTSTG**Q**) of SEQ ID NO:12. GenPept BAC17521 does not include either of these two sequence of 8 consecutive amino acids from SEQ ID NO:12. Therefore, GenPept BAC17521 does not anticipate the claims. Applicant submits that the amended claims are sufficiently clear and overcome the anticipation rejection. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b).

IX. Rejections Under 35 U.S.C. § 103(a): Non-obviousness over Quinnan *et al.* (WO 00/07631 - supra)

Applicant thanks the Examiner for withdrawing the previous rejection of claims 34 and 35 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Quinnan *et al.* (WO 00/07631). See Office Action, page 8.

X. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: October 8, 2009

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